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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/766,134	01/27/2004	George N. Serbedzija	018852-000610US	1970

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EXAMINER	
BERTOGLIO, VALARIE E	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 09/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/766,134	SERBEDZIJA ET AL.	
	Examiner	Art Unit	
	Valarie Bertoglio	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *67-84* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *67-84* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *01/27/2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *04/22/2005;06/29/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's preliminary amendment filed 03/15/2006, has been entered. Claims 1-66 have been cancelled. Claims 67-84 are pending and under consideration in the instant office action.

Priority

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The current status of all nonprovisional parent applications referenced should be included or updated. The current reference fails to indicate the status of parent application 09/451,489 as allowed.

Specification

The disclosure is objected to because of the following informalities:

Page 3 at line 1 appears to have a typographical error in that it reads "...markers, r, survival...".

Page 23 at line 9 appears to have a typographical error. It appears that "BRU" should read "BRDU".

Appropriate correction is required.

Claim Rejections - 35 USC § 112-1st paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Enablement

Claims 67-76 and 78-83 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of analyzing a sample comprising cells for the presence of a cancer cell comprising obtaining a sample from a patient containing a cell or a population of cells, introducing the cell or the population of cells into an embryo of an oviparous fish species that has not yet developed an immune system that would subject the cancer cells to immune rejection, and detecting a property of the cell or the population of cells to indicate whether the cell or the population of cells comprises a cancer cell does not reasonably provide enablement for analyzing a cell or population of cells for the presence of a pathogen by detecting a property of the pathogen or for carrying out the claimed method in any viviparous fish species. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

It is noted that the enabled scope set forth above is not intended as suggested claim language but indicates the broadest enabled scope. The specification does not appear to support the use of the term "oviparous". Applicant should use terminology within this scope that is supported by the specification.

Enablement is considered in view of the Wands factors (MPEP 2164.01(a)). The court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as

routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' " (*Wands*, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (*Wands*, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. While all of these factors are considered, a sufficient amount for a *prima facie* case are discussed below.

Claims are directed to methods of cellular analysis comprising introducing one or more cells into a fish embryo and analyzing a property of the transplanted cells to determine the presence of a cancerous cell. Limiting embodiments to the parent claim include the source of the cells, the species of fish embryo used, the placement within the embryo of the heterologous cells, and various analysis steps including determining proliferation, death, metastasis, cellular uptake of dyes indicating cell to be cancerous and expression of proteins indicative of cancerous cells.

The claims broadly encompass use of embryos from any species of fish. The specification has contemplated specifically zebrafish, medaka, Giant rerio or pufferfish, which are oviparous

species, for use in the instant invention. The specification does not teach how to carry out the claimed method using other species of fish, especially viviparous species of fish wherein the embryo develops inside the mother. Use of viviparous fish would require removal of embryos from the mother and culturing them outside the mother. The specification and the art of record fail to address how one would carry out such a task. The usefulness of the invention relies on visualizing cells within the embryo, which would require culture of embryos in vitro. Transfer of the embryos back to the mother in viviparous species, if even possible, would conceal them from view. Therefore, one of skill in the art would not know how to carry out the instant invention in fish species other than oviparous species.

The claims are also drawn to determining whether the transplanted cells contain a pathogen. The specification fails to provide the guidance necessary to carry out the claims as they related to determing to whether the transplanted cells contain a pathogen. The specification refers to this embodiment of the invention at page 16 in teaching that bacterial cells or fungal cells can be transplanted into an embryo and the resulting embryo used to screen agents for toxicity on the pathogenic cells (page 16, paragraph 20). However, this does not teach how to determine the presence of a pathogen in a sample. Page 19, paragraph 1 mentions transplanting cells and culturing them in a fish embryo to amplify a pathogen, facilitating detection. However, the specification does not teach or even contemplate how to transplant cells comprising a pathogen without causing death of the embryo or how one would detect a pathogen. Teachings regarding use of the claimed method in detecting a pathogen are limited. No guidance regarding this embodiment was found other than at pages 16 and 19 as set forth above.

Claims 77 and 84 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 77 and 84 limit the scope of claim 67 to a non-enabled embodiment. As set forth above, the specification fails to enable the analysis for the presence of a pathogen. Because the scope of claims 77 and 84 are limited to this embodiment, they are not enabled.

Written Description

Claim 81 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116).

The claimed invention as a whole is not adequately described if the claims require essential or critical elements that are not adequately described in the specification and that is not conventional in the art as of applicants effective filing date. Possession may be shown by actual reduction to practice, clear depiction of the invention in a detailed drawing, or by describing the

invention with sufficient relevant identifying characteristics such that a person skilled in the art would recognize that the inventor had possession of the claimed invention. Pfaff v. Wells Electronics, Inc., 48 USPQ2d 1641,1646 (1998).

In the instant case dyes specifically taken up by cancer cells encompassed by the claim lacks a written description. The specification fails to describe what dyes fall into this genus. The specification has described labels conjugated to cancer-specific markers; however, the specification has not described a single dye that is taken up specifically by cancer cells.

The skilled artisan cannot envision the detailed chemical structure of the encompassed dyes, and therefore conception is not achieved regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Claim Rejections - 35 USC § 112-2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 73 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 73 is unclear because it requires injection into the blastula of the embryos. It is not clear if the claim is referring to a specific part of the embryo or if it is referring to the blastula

stage embryo. If the latter is the case, the claim would be clearer if it read, "microinjected into a blastula stage embryo".

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 83 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1,33,40 and 16 of U.S. Patent No. 6,761,876. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 83 of the instant application is drawn to a method of testing an antineoplastic procedure, which is generic to and encompasses administering an agent as claimed in claims 1,16,33 and 40 of '876. Thus, claim 83 is anticipated by claims 1,16,33 and of '876.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Valarie Bertoglio whose telephone number is (571) 272-0725. The examiner can normally be reached on Mon-Thurs 5:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone numbers for the organization where this application or proceeding is assigned are (571) 273-8300 for regular communications and (571) 273-8300 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-0532.

Valarie Bertoglio
Examiner
Art Unit 1632